

**DIPHENHYDRAMINE HYDROCHLORIDE- diphenhydramine hydrochloride tablet,  
film coated  
Elysium Pharmaceuticals Ltd**

**Diphenhydramine Hydrochloride**

**PRINCIPAL DISPLAY PANEL**

<b>DIPHENHYDRAMINE HYDROCHLORIDE TABLETS 25 mg (PINK)</b>			
Each Film Coated Tablet Contains : Diphenhydramine Hydrochloride USP 25 mg			
Batch No. :	Shipper No. :		
Mfg. Date :	Quantity :	1,00,000 Tablets	
Exp. Date :	NDC No. :	14803-273-00	"S4" DEBOSSED
<b>WARNING: KEEP OUT OF THE REACH OF CHILDREN</b>		Manufactured By :	
STORE AT USP CONTROLLED ROOM TEMPERATURE OF 59° TO 86° F (15° TO 30° C) PROTECT FROM LIGHT, MOISTURE AND FREEZING.		 elysium PHARMACEUTICALS LTD.	MANUFACTURER CODE No.: Guj/Drugs/G/1362 LABELER CODE # 14803
THIS IS A BULK SHIPMENT INTENDED FOR FURTHER PROCESSING ONLY. CONTENTS SHOULD BE APPROVED, REPACKAGED IMMEDIATELY AND LABELED IN STRICT CONFORMANCE WITH THE FD&C ACT AND REGULATIONS THEREUNDER.		Manufactured For : <b>InvaTech Pharma Solutions LLC</b> 40 C Cotters Lane, Suite # A, East Brunswick, NJ 08816 PH # 732-307-7926 FAX # 732-307-7931	
<b>CAUTION : "FOR MANUFACTURING, PROCESSING OR REPACKAGING"</b>			

**DIPHENHYDRAMINE HYDROCHLORIDE**

diphenhydramine hydrochloride tablet, film coated

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDc:14803-273
<b>Route of Administration</b>	ORAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	25 mg

**Inactive Ingredients**

Ingredient Name	Strength
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>CROSCARMELLOSE SODIUM</b> (UNII: M28OL1HH48)	
<b>CALCIUM PHOSPHATE, DIBASIC, ANHYDROUS</b> (UNII: L11K75P92J)	
<b>D&amp;C RED NO. 17</b> (UNII: ND733RX3JN)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>CELLULOSE, MICROCRYSTALLINE</b> (UNII: OP1R32D61U)	
<b>POLYVINYL ALCOHOL</b> (UNII: 532B59J990)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>TALC</b> (UNII: 7SEV7J4R1U)	
<b>LECITHIN, SOYBEAN</b> (UNII: 1DI56QDM62)	

### Product Characteristics

<b>Color</b>	pink	<b>Score</b>	no score
<b>Shape</b>	CAPSULE	<b>Size</b>	11mm
<b>Flavor</b>		<b>Imprint Code</b>	S4
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:14803-273-00	100000 in 1 BOTTLE; Type 0: Not a Combination Product	03/07/2024	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	03/07/2024	

**Labeler** - Elysium Pharmaceuticals Ltd (915664486)

### Establishment

Name	Address	ID/FEI	Business Operations
Elysium Pharmaceuticals Ltd.		915664486	manufacture(14803-273) , analysis(14803-273)

Revised: 1/2026

Elysium Pharmaceuticals Ltd